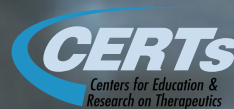


CERTs Annual Report

October 1, 2010 –
September 30, 2011



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Centers for Education &
Research on Therapeutics

Centers for Education and Research on Therapeutics (CERTs) Annual Report

October 1, 2010–September 30, 2011

Introduction

This report summarizes the work of the Centers for Education & Research on Therapeutics (CERTs) for October 2010 through September 2011. During this period, 14 CERTs research centers and 1 CERTs coordinating center were funded through cooperative agreements with the Agency for Healthcare Research and Quality (AHRQ). In addition to describing specific projects and accomplishments for 2010–2011, this report provides summary background information about the purpose and components of the overall CERTs Program.

The CERTs program of cooperative agreements is funded and managed by the Agency for Healthcare Research and Quality (AHRQ) in consultation with the U.S. Food and Drug Administration (FDA). The CERTs receive funds from both public and private sources, with AHRQ providing core financial support.

Program Purpose

The CERTs program is a national initiative established in 1999 to conduct research and provide education that advances the optimal use of drugs, medical devices, and biological products, collectively described as “therapeutics.” The CERTs program has three major aims that were established by Congress:

1. **To increase awareness** of both the uses and risks of new drugs and drug combinations, biological products, and devices, as well as of mechanisms to improve their safe and effective use.
2. **To provide objective clinical information** to patients and consumers; health care providers; pharmacists, pharmacy benefit managers, and purchasers; health maintenance organizations (HMOs) and health care delivery systems; insurers; and government agencies.
3. **To improve quality while reducing cost of care** by increasing the appropriate use of drugs, biological products, and devices and by preventing their adverse effects and consequences of these effects (such as unnecessary hospitalizations).

The CERTs are also authorized to conduct research on the comparative effectiveness, cost-effectiveness, and safety of therapeutics.

Program Components

In addition to the AHRQ-funded research centers and coordinating center, the CERTs network includes a steering committee and numerous partnerships with public and private organizations dedicated to improving the quality and safety of therapeutics. The steering committee offers guidance to the coordinating center and research centers and includes representatives from the drug and device Centers of the Food and Drug Administration, each research center's principal investigator, an at-large representative of Federal health agencies, and leaders in health care, private industry, and consumer advocacy. These diverse stakeholder perspectives ensure that the CERTs remain well informed and on the cutting edge of significant and emerging health care issues.

The coordinating center provides overall support for the CERTs program through strategic planning, program development, and outreach. The coordinating center plays a key role in establishing relationships and collaborations with multiple partners whose needs, data, or dissemination and implementation activities can further CERTs research. Partnerships are cultivated with public and private entities to help the CERTs leverage their funded research into additional projects and to extend their impact. All public-private partnerships are reviewed for potential conflicts of interest using established CERT principles and practices.

Each CERTs research center organizes its research and educational activities within a defined thematic area of therapeutics, which may represent a vulnerable population, a group of related medical conditions, or a specific methodologic approach or tool such as delivery systems or health information technology.

Between 2010 and 2011, the 14 CERTs research centers represented a wide variety of thematic foci and worked with the support of the CERTs coordinating center at the Kaiser Permanente Center for Health Research in Portland, Oregon, led by its Principal Investigator Mark Hornbrook, Ph.D. The 14 research centers are listed in Table 1 with their thematic focus and Principal Investigator's name.

Table 1. CERTs Research Centers 2010-2011

CERTs Research Centers	Thematic Focus	Principal Investigator
Brigham and Women's Hospital	Health Information Technology	David Bates, M.D., M.Sc.
Cincinnati Children's Hospital Medical Center	Pediatric Therapeutics	Carole Lannon, M.D., M.P.H.
Duke University Medical Center	Therapies for Heart and Blood Vessel Disorders	Eric Peterson, M.D., M.P.H.

CERTs Research Centers	Thematic Focus	Principal Investigator
HMO Research Network	Multiple Population-Based Delivery Systems	Richard Platt, M.D., M.S.
Rutgers, The State University of New Jersey	Mental Health Therapeutics	Stephen Crystal, Ph.D.
University of Alabama at Birmingham	Musculoskeletal Disorders	Kenneth Saag, M.D., M.Sc.
University of Arizona CERT at the Critical Path Institute	Drug Interactions/Women's Health	Raymond Woosley, M.D., Ph.D.
University of Chicago	Clinical, Economic Issues in Hospital Settings	David Meltzer, M.D., Ph.D.
University of Illinois at Chicago	Prescribing Tools, Including Formularies	Bruce Lambert, Ph.D.
University of Iowa	Elderly and Aging	Elizabeth Chrischilles, Ph.D.
University of Pennsylvania School of Medicine	Anti-Infective Use and Resistance	Brian Strom, M.D., M.P.H.
University of Texas M.D. Anderson Cancer Center and Baylor College of Medicine (Houston CERT)	Consumer Education and Patient Adherence	Maria Suarez-Almazor, M.D., Ph.D.
Vanderbilt University	Therapeutic Issues in Medicaid and VA Systems	Wayne Ray, Ph.D.
Weill Medical College at Cornell University	Therapeutic Medical Devices	Alvin Mushlin, M.D., Sc.M.

Program Activities 2010–2011

The 14 CERTs research centers covered a broad range of pressing issues in health care, from investigating potentially dangerous drug interactions to studying therapies for vulnerable patients—including children with chronic illnesses, the severely mentally ill, and the elderly—to

evaluating promising tools in health information technology. In addition to research, the centers took a leading role in providing evidence-based, objective information to educate patients, doctors, pharmacists, health plans, and others about the drugs, devices, and biological products that play an important role in our daily lives.

The following sections highlight many of the research and educational projects completed between September 2010 and October 2011, organized by Center and with lists of all resulting CERTs publications in peer-reviewed scientific journals. Submitted publications may have publication dates after 2011 based upon an update of this document through March 2013.

Brigham and Women's Hospital

The Brigham and Women's Hospital CERT focused on Health Information Technology (health IT) to evaluate the effects on clinical care and patient outcomes of electronic medical records, computerized provider order entry, and other technologies to support health professionals in making clinical decisions. Researchers at the Brigham and Women's CERT study the effects of health IT interventions to improve safety and quality as well as minimize medication errors for outpatients, inpatients, and patients who are recently discharged from hospitals.

Errors Associated with Computerized Prescribing Systems. Computerized prescribing systems are becoming more common, but do they reduce prescribing errors? Brigham and Women's CERT researchers examined the frequency, types, and causes of errors associated with outpatient computer-generated prescriptions, and to determine how best to prevent them. The researchers examined and analyzed 3,850 computer-generated prescriptions from a commercial outpatient pharmacy chain across three states over 4 weeks. A panel of clinicians reviewed the prescriptions to identify and classify medication errors. Of 3,850 prescriptions, 452 (11.7 percent) contained 466 errors, of which 163 (35.0 percent) were considered potential adverse drug events. Error rates varied by prescribing system, from 5.1 percent to 37.5 percent. The most common error was omitted information (60.7 percent). About 1 in 10 prescriptions included at least one error, of which a third had potential for harm. These error rates were consistent with error rates for handwritten prescriptions. The number, type, and severity of errors varied by prescribing system suggesting that some systems may be better at preventing errors. The authors offered targeted recommendations for improving computerized prescribing systems to prevent errors.

Nanji, KC, Rothschild JM, Salzberg, C, et al. Errors associated with computerized prescribing systems. *J Am Med Inform Assoc* 2011;18:767-773.

Cincinnati Children's Hospital Medical Center

The Cincinnati Children's Hospital Medical Center (CCHMC) CERT focused exclusively on children in studying the safe and effective use of medications. Two themes were patient safety and improving outcomes through the use of multi-site clinical specialty networks for research and improvement. Researchers also studied how understanding a child's genetic makeup can help clinicians select appropriate drugs and dosages. Since 2007, the CERT has supported a collaborative project to improve care for children with Crohn's disease and ulcerative colitis—two painful and debilitating bowel conditions. This program, called ImproveCareNow, is helping

children who suffer from these conditions to feel better and move into remission. Building on the lessons learned from this work, the CCHMC CERTs also supported national multisite research and improvement networks for infants with congenital heart disease and children with juvenile idiopathic arthritis. Project teams included clinicians and researchers at 94 sites across 35 States and Washington DC; London, United Kingdom; and Toronto, Canada; and 44 Clinical and Translational Science Awards Institutions. Many of the networks have already shown improvements in care delivery and outcomes for children as described below.

Solutions for Patient Safety. In this project, all eight Ohio children's hospitals began collaborating to improve outcomes in medication safety and surgical site infections. Between January 2009 and December 2010, the project resulted in a 60 percent reduction in surgical site infections in designated procedures and a 34.5 percent reduction in overall adverse drug events, saving an estimated 3,576 children from harm and over \$5.2 million. This public-private partnership planned to continue with a focus on reducing eight types of harm by 50 percent in the next 24 months. The initial pilot work funded by CERTs was leveraged and expanded with grants to the Ohio Children's Hospital Association from Cardinal Health, an example of the potential benefits gained through CERTs public-private partnerships.

Pediatric Rheumatology—Care and Outcomes Improvement Network. This project focused on improving outcomes for children with juvenile idiopathic arthritis. Eleven teams developed interventions for tuberculosis screening, uveitis (inflammation of the inner eye), and joint count (counting the number of swollen and tender joints), as well as monthly registry data collection. The network will continue to develop and evaluate specific disease management strategies to improve care and determine how best to incorporate these strategies into clinical practice. This work was funded by CERTs and leveraged additional support from an anonymous family foundation.

Vermaire D, Caruso MC, Lesko A, et al. Quality improvement project to reduce perioperative opioid oversedation events in a paediatric hospital. *BMJ Qual Saf* 2011 Oct;20(10):895-902.

Lannon CM, Peterson L, Goudie A. Quality Measures for the care of children with otitis media with effusion. *Pediatrics* 2011 Jun;127(6):e1490-7.

Duke University Medical Center

The Duke CERT focused on cardiovascular (CV) disease—the leading cause of illness and death in the United States, and, at a cost of \$475 billion per year, the most expensive medical condition to treat. Duke's CERT team identified gaps in CV care and their consequences, generated evidence on the safety and effectiveness of treatments, and translated knowledge into practice through work with providers around the country.

For example, the Duke CERT collaborated with national registries such as Get With the Guidelines (GWTG), a program launched in 2000 by the American Heart Association, to help health care facilities measure and improve care for patients with acute coronary syndromes, stroke and heart failure. GWTG represented more than 1,600 participating hospitals. To improve outcomes for patients, the Duke CERT has published papers on gaps and disparities in care and

the comparative effectiveness of treatments, identified factors that affect whether patients take medications as prescribed, and created feedback reports for participating hospitals on their adherence to guidelines. Such evidence can be used to modify providers' behavior and educate patients.

Investigating Factors Associated with Rapid Stroke Treatment. Duke CERT researchers investigated factors associated with rapidly treating ischemic stroke, the most common type of stroke, which occurs when a blood vessel that supplies the brain is blocked. Use of a treatment called recombinant tissue plasminogen activator (rt-PA) has been shown to improve clinical outcomes if used within 4.5 hours after stroke onset. Through open-ended interviews with staff from high performing hospitals, Duke CERT researchers identified factors that allowed these hospitals to meet treatment goals for a high percentage of eligible patients. These factors included: 1) communication and teamwork; 2) clear treatment protocols; 3) a supportive organizational culture; 4) performance monitoring and feedback; and, 5) identifying and overcoming barriers.

Olson DW, Constable M, Britz GW, et al. A qualitative assessment of practices associated with shorter door-to-needle time for thrombolytic therapy in acute ischemic stroke. *J Neurosci Nurs* 2011 Dec;43(6):329-36.

Linking Clinical Registries to Medicare Data. This Duke project linked four national clinical registries to Medicare data to evaluate long-term outcomes for patients with acute coronary syndromes (diseases involving the coronary arteries) and heart failure. In contrast to data gathered in controlled clinical trials, these data provide a "real world" look at the use of medications, procedures, and patients' outcomes. Duke researchers used these data to examine whether there was an association between treatment at hospitals that adhere more closely to care quality measures (these include use of specific treatments and medications in the hospital, discharge education, and prescription of evidence-based medications upon discharge) and lower rates of hospital readmission and death. For example, patients with heart failure who followed up with a physician within a week of hospital discharge had lower rates of re-hospitalization within 30 days. In another study, Duke researchers found that Medicare patients with heart failure who were eligible for an implantable cardioverter-defibrillator (ICD) and who received an ICD had a lower risk of death over the following three years than those who did not receive a device.

Hernandez AF, Hammill BG, Peterson ED et al. Relationships between emerging measures of heart failure processes of care and clinical outcomes. *Am Heart J* 2010;159(3):406-413.

Hernandez AF, Greiner MA, Fonarow GC et al. Relationship between early physician follow-up and 30-day readmission among Medicare beneficiaries hospitalized for heart failure. *JAMA* 2010;303(17):1716-22.

Hernandez AF, Fonarow GC, Hammill BG et al. Clinical effectiveness of implantable cardioverter-defibrillators among medicare beneficiaries with heart failure. *Circ Heart Fail* 2010;3(1):7-13.

HMO Research Network

The HMO Research Network (HMORN) CERT focused on the use, safety, and effectiveness of drugs in managed care settings by bringing together the public domain research units of 13 health plans providing health care for a geographically diverse sample of more than 11 million

U.S. citizens. It included six health plans that were also part of the Kaiser Permanente Center for Effectiveness and Safety Research. The HMORN CERT's mission was advancing overall public health by increasing understanding about best therapeutics practices and disseminating that knowledge widely through its member health plans' defined populations, large provider groups, and unique data sources.

Examining How Age, Sex, Race, Smoking, and Obesity affect Risk of Serious Infections Associated with Anti-Tumor Necrosis Factor Drugs. Anti-tumor necrosis factor (anti-TNF) drugs are used to treat inflammatory conditions such as rheumatoid arthritis and psoriasis. HMORN CERT researchers assessed how patients' age, sex, race or ethnicity, body mass index, and smoking status affected their risk of getting a serious infection after using the anti-TNF agents infliximab (Remicade), and etanercept (Enbrel). Using the electronic health records of 3,485 patients, the researchers established linkages to drug dispensing and administrative data, as well as eligibility and outcome data. In the year after patients began treatment, the researchers found 176 serious infections. Of all the characteristics the researchers examined, only age affected the risk of infection associated with these two drugs. There was an increased risk of serious infections associated with infliximab for patients younger than 65 years, but not for patients 65 or older.

Toh S, Li L, Harrold LR, et al. Comparative safety of infliximab and etanercept on the risk of serious infections: does the association vary by patient characteristics? *Pharmacoepidemiol Drug Saf* 2012 May;21(5):524-34.

Rutgers, The State University of New Jersey

The Rutgers Mental Health CERT focused on improving the safety and effectiveness of treatments for mental health problems. The Rutgers CERT partnered with the American Psychiatric Association and Columbia University to build an extensive database to allow researchers to address a range of mental health issues, including the safe and effective use of psychotropic drugs and antidepressants, especially among young people and the elderly. This CERT's educational initiatives included quality-improvement collaborations with State mental health and Medicaid officials, and developing national treatment guidelines. Ultimately, all of the Rutgers CERT efforts sought to improve care and outcomes for people who receive treatment for mental health problems.

Comparing Treatments for Early-Onset Schizophrenia. Early-onset schizophrenia (the appearance of schizophrenia prior to age 18) is often severely impairing, but little is known about which drugs work best to manage it. Rutgers CERT researchers studied Medicaid data from 45 States to examine differences in the use of newer antipsychotic drugs among children and adolescents with schizophrenia. They found that treatment with each of the medications was associated with a high risk of stopping treatment early and admission to a psychiatric hospital within 6 months of starting. No prior study had compared antipsychotic medications in early-onset schizophrenia in terms of treatment discontinuations and time to hospitalizations.

Olfson M, Gerhard T, Huang C, et al. Comparative effectiveness of second-generation antipsychotic medications in early-onset schizophrenia. *Schizophr Bull* 2012 Jun;38(4):845-53.

University of Alabama at Birmingham

The University of Alabama at Birmingham Deep South Musculoskeletal CERT aimed to improve the safety and effectiveness of musculoskeletal therapeutics, educate health care practitioners, insurers, and policy makers, and broaden the impact of musculoskeletal research on public health.

Safety Assessment of Biologic Therapy Collaborative (SABER). Although biologic treatments are effective for many autoimmune diseases, concerns exist about their safety. The Safety Assessment of Biologic ThERapy Collaborative (SABER) involved five CERT research centers to better understand how serious adverse events may be connected with anti-Tumor Necrosis Factor (TNF) therapies. The SABER collaborative was funded to study and report on risks of adverse events among anti-TNF users using data from national Medicare and Medicaid programs, Tennessee Medicaid, the Kaiser Permanente health plans, and State pharmaceutical assistance programs that supplement the New Jersey and Pennsylvania Medicare programs. This study, which used data from 1998-2007, examined risks of seven classes of adverse events in relation to anti-TNF treatments prescribed for seven autoimmune diseases. The cohort consisted of 159,000 subjects with rheumatic diseases, 33,000 with psoriasis, and 46,000 with inflammatory bowel disease. In 2010-2011, CERT researchers reported on this group's demographic characteristics and drug exposures using a method to maintain the privacy of each component data base that they used. Future reports will estimate the risks for adverse events associated with these medicines.

Rassen JA, Solomon DH, Curtis JR, et al. Privacy-maintaining propensity score-based pooling of multiple databases applied to a study of biologics. *Med Care* 2010 June; 48(6 Suppl): S83-S89.

Allowing Self-Referrals for Osteoporosis Screening Improves Testing Rates. Researchers from the UAB CERTs, in collaboration with their counterparts from Kaiser Permanente Northwest and Kaiser Permanente Georgia, have found that among Medicare-eligible women, allowing self-referral for a bone density test known as DXA (the central dual energy x-ray absorptiometry test) significantly improves osteoporosis screening rates. Current U.S. guidelines recommend bone density screening with DXA in all women 65 years or older. However, less than one-third of eligible U.S. women receive this test. In an effort to identify a systematic approach to improve rates of DXA testing, researchers at UAB randomized primary care clinics either to allow women to self-schedule a DXA (similar to mammography self-scheduling) or to continue usual care.

Initial results indicated that DXA scan scheduling and receipt improved significantly by allowing patients to self-schedule (31.3 percent) versus usual care (11.1 percent). Providing eligible women the opportunity to self-schedule a DXA scan may be an effective, low-cost strategy to increase rates of osteoporosis screening.

Warriner A, Outman R, Curtis J, et al. DXA Screening and use of osteoporosis medications in two large healthcare systems. *J Bone Miner Res* 2010; 25(Suppl S1):S450-S451.

Warriner, A, Outman, RC, Curtis, JR., et al. DXA screening and use of osteoporosis medications in two large regional healthcare systems. *Arthritis Rheum* 2010; 62(Suppl 10):1543.

University of Arizona CERT at C-Path

The Arizona CERT, a program of the Critical Path Institute in collaboration with the University of Arizona College of Pharmacy, focused on preventing adverse drug events, especially those that harm women. Center researchers focused on drugs and drug interactions that prolong the QT interval—a measure of the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle, as shown on an electrocardiogram. A prolonged QT interval is a risk factor for torsade de pointes, a ventricular heart arrhythmia that can cause sudden death. Patients who have a rare heart condition that increases the risk of episodes of torsade de pointes—congenital Long QT Syndrome—are at the greatest risk of harm from drugs that prolong the QT interval.

Preventing Drug-Induced Heart Rhythm Disturbances. To help doctors and patients be aware of the drugs and drug interactions that can cause QT prolongation, the Arizona CERT maintained a web-based resource, www.QTdrugs.org, with up-to-date lists of medications that prolong the QT interval categorized according to their known, possible, or conditional risk of causing life-threatening heart arrhythmias. This resource allowed doctors and patients anywhere in the world to stay informed about QT-prolonging drugs. In addition, this website allowed clinicians and pharmacists to alert the Arizona CERT about drugs that may be causing QT problems. Methadone, a drug used for more than forty years in the U.S. to treat heroin addiction and pain, was reported to the center as a potential cause of QT prolongation, became a high priority for research, and was found to produce life-threatening arrhythmias—bringing to light a major patient safety issue.

AzCERT investigators continually monitored data and alerts for drugs that may cause QT prolongation and applied a systematic approach to analyzing the available evidence. In 2011, www.QTdrugs.org was updated for vendetanib (Caprelsa), flecainide (Tambocor), dronedarone (Multaq), and escitalopram (Lexapro) and received approximately 2,600 page views daily.

Pharmacy Systems Fail to Identify Drug-Drug Interactions. While the pharmacy is a major line of defense for the prevention of potential drug-drug interactions (DDIs), AzCERT research in 2011 suggested that pharmacy computer software programs designed to prevent such interactions—called clinical decision support (CDS) systems—do not perform as well as they should. AzCERT researchers studied 64 pharmacies in Arizona and found that only 28 percent of pharmacies' CDS software programs correctly identified potentially dangerous drug-drug interactions. Investigators tested the pharmacies' CDS systems using prescription orders for a fictitious patient with 18 different drugs, which posed 13 clinically significant DDIs. This work led to the development of a tool that allows pharmacies and other organizations to check their software to determine if significant gaps or problems exist.

Warholak TL, Hines LE, Saverno KR, et al. Assessment tool for pharmacy drug-drug interaction software. *J Am Pharm Assoc* (2003) 2011 May;51(3):418-24.

Educating Prescribers about Safe Practices. In 2011, the AzCERT developed multiple education products for students, pharmacists and clinicians about safe prescribing practices. They launched an interactive Continuing Medical Education module targeted to prescribers with the highest rates of writing inappropriate co-prescriptions for interacting drugs, collaborated with FDA on a continuing education module, *Preventing Adverse Drug Events: A Focus on Drug Interactions*, and worked with the Houston CERT on an educational module on genetic variants and how they are associated with clinical outcomes for patients who are taking clopidogrel (Plavix). Other partners included the American Association of Medical Colleges (to disseminate CERTs educational products to medical schools throughout the country) and the American Medical Association, with whom the AzCERT developed a brochure to promote safe use of abacavir (Ziagen®), codeine, clopidogrel (Plavix®), and warfarin (Coumadin®). Also, the AzCERT developed MyMedsList, an iPhone application that builds on the capabilities of the existing web-based My Medications Tool (available at www.mymedslist.org). The new app enables patients to create a record of their medications with information on their prescribers and pharmacies; it can also be sent as an email attachment to health care providers.

University of Chicago

The University of Chicago CERT sought to improve the effectiveness and cost-effectiveness of hospital-based therapeutics. Over the past quarter century, hospitals have had to adapt to address new clinical and economic challenges. Hospitals are increasingly using clinical information systems and complex systems approaches to improving safety and quality. There has also been rapid growth in the number of physicians specializing in hospital care. Researchers at the UC CERT used the tools of economics and social science to analyze and help solve the complex problems that arise in modern-day hospital care.

Laying the Groundwork for Comparative Effectiveness Research in Hospitals. The need for comparative effectiveness research (CER) has highlighted the importance of underlying data infrastructures to support that research. In 2011, the UC CERT, in partnership with University HealthSystem Consortium (UHC), led a collaboration of Chicago area teaching hospitals to develop infrastructure to support hospital-based CER. This infrastructure effort will contribute electronic health record data to UHC's existing database and provide a shared clinical research coordinator to facilitate study recruitment at multiple sites. This investment will pave the way for studies and applications of data on inpatient outcomes, quality, cost, and medical education to academic medical centers nationwide. Previous UC CERT studies examining hospital outcomes for vulnerable elders, effects of residency duty hours, off-label prescribing in the inpatient setting, and efforts to improve the effective use of inhalers will be enriched and by the multicenter studies enabled by the new infrastructure.

University of Illinois-Chicago

The University of Illinois at Chicago CERT focused on tools for optimizing the prescribing of drugs, monitoring drugs once they are prescribed, and educating pharmacists and clinicians about better prescribing practices. The CERT studied ways to prevent medication errors, particularly in projects that linked together disconnected hospital data systems—for example, pulling in data from patients' lab tests to inform the ordering of diagnostic tests or medications. Researchers

have also tested automated alerts that warn clinicians of potential errors as they enter their orders into computer systems.

CERT researchers educated students, medical residents, and physicians about the role of formulary committees that decide which prescription drugs a health-care plan will cover. Researchers also gave presentations on “principles of conservative prescribing” to a variety of audiences, and created a course for pharmacy students on critical analysis of pharmaceutical marketing materials.

Creating a Monitoring and Alert System. In 2011, building on previous work in which researchers at the UIC CERT developed a set of 24 “high priority pairs” of medications and laboratory results to monitor, researchers and other CERT team members put these findings to practical use programming these pairs into the clinical computer system at the University of Illinois hospital to provide pharmacists and doctors with daily alerts about situations in which patients’ medications might be risky or when patients could be suffering an adverse event from medication. UIC CERT researchers have also disseminated this monitoring and alert system to other hospitals and are in the process of measuring its impact.

Yu S, Galanter WL, DiDomenico RJ, et al. Selection of drug-laboratory result pairs for an inpatient asynchronous alert program: results of a Delphi survey. *Am J Health Syst Pharm* 2011 Mar 1;68(5):407-14.

University of Iowa

The University of Iowa Older Adults CERT focused on improving the safety and effectiveness of medications for elderly people. Members of this group are vulnerable to medication problems for several reasons. They are under-represented in randomized clinical trials, which are used to test the safety and effectiveness of new medicines. They are at increased risk of side effects because they often have several co-occurring conditions, for which they take numerous medications and frequently see different physicians. Together, these pose a greater risk of medication interactions and duplications. The normal aging process itself can decrease the body's ability to metabolize medications. For all of these reasons, it is important that researchers find ways to monitor and optimize the safety and effectiveness of therapeutics for the elderly.

Doctor-pharmacist teams improve blood pressure control. High blood pressure, also known as hypertension, is a major cause of illness and death in the United States. University of Iowa CERT researchers have found that when doctors and pharmacists work together to monitor patients’ blood pressure, they can improve blood pressure control, and the improvements are long lasting. They conducted a study to test how well a collaboration between pharmacists and doctors worked to help people control their blood pressure. The researchers evaluated blood pressure control among two groups of patients 18 months after a program using doctor-pharmacist teams ended. The researchers hypothesized that patients who had received treatment from the teams would have better control of blood pressure compared to patients who received usual care. The study found that blood pressure control rates remained significantly higher following the team intervention compared with blood pressure among patients who had usual care, even 18 months after the program ended. This approach may hold potential as a useful long-term strategy to benefit patients with hypertension.

Wentzlaff DM, Carter BL, Ardery G, et al. Sustained blood pressure control following discontinuation of a pharmacist intervention. *J Clin Hypertens (Greenwich)* 2011 Jun;13(6):431-7.

University of Pennsylvania School of Medicine

The PennCERT was part of the Center for Clinical Epidemiology and Biostatistics at the University of Pennsylvania School of Medicine. The CERT's overall mission was to decrease the inappropriate use of antibiotics and combat the emergence of bacteria that are resistant to antibiotics, a major public health concern. Researchers focused on infectious diseases and anti-infective therapy, seeking to inform decisions about anti-infective drugs, to evaluate interventions aimed at reducing inappropriate use of anti-infective agents, and to disseminate the results of their research. In addition, the PennCERT had three research foci: pharmacoepidemiology, patient safety, and health information technology.

Use of Antibiotics in Childhood a Risk Factor for Later Inflammatory Bowel Disease.

While the causes of inflammatory bowel disease (IBD) remain unclear, prior studies have suggested that antibiotic exposure may contribute to its development. UPenn CERT researchers studied the health data of more than one million children from more than 450 outpatient clinical practices in the U.K. and found that exposure to anti-anaerobic antibiotics was associated with developing IBD throughout childhood. This apparent relationship decreased for children who had their initial antibiotic exposure at an older age. The hazard of developing IBD was greatest with exposure to anti-anaerobic antibiotics prior to one year of age, which was twice that of those children exposed by 5 years of age. Additionally, each antibiotic course increased the hazard of developing IBD by 6 percent. The researchers noted these findings add further stimulus for reducing unnecessary antibiotic use during childhood.

Kronman MP, Zaoutis TE, Haynes K, et al. Antibiotic exposure and IBD development among children: a population-based cohort study. *Pediatrics* 2012 Oct;130(4):e794-e803.

University of Texas M.D. Anderson Cancer Center and Baylor College of Medicine (Houston CERT)

The Houston CERT was a collaboration between the University of Texas M.D. Anderson Cancer Center and Baylor College of Medicine. Its mission was to promote informed decision-making—to help health care consumers and their providers make better decisions by providing information about the benefits and risks of therapeutics. A primary focus was to promote improved patient and provider adherence to care and to care guidelines. The Houston CERT also produced the Consumer Health Advisory Information Network (CHAIN) website, www.chainonline.org, a clearinghouse for all the CERTs to provide information to health care professionals, patients, family members, and the public about new and pressing issues related to the safety and efficacy of drugs, devices, and biological products. For example, the Houston CERT developed a portal on the CHAIN Online website about emerging drug therapy guidelines for drug-eluting stents.

Understanding Patient Choices in Joint Replacement. In 2011, Houston CERT researchers developed and tested a computerized tool for patients considering surgery to replace a knee joint. The adaptive conjoint analysis (ACA) tool was designed to help a patient in

clarifying his or her overall values and preferences by making a series of choices. Researchers conducted a pilot study to evaluate the ACA tool for feasibility and patient satisfaction and then evaluated the tool in a randomized trial of patients with knee osteoarthritis. The trial compared three interventions: 1) printed educational materials; 2) printed materials plus an educational DVD; and 3) printed materials, a DVD, and the new ACA computerized decision tool. Statistical analysis indicated that all of the groups' conflict in making decisions was reduced, but the largest reduction was among those who viewed the DVD alone, suggesting that the additional ACA tool did not improve decision-making. A subsequent study of the ACA tool to aid patients over the age of 65 in making treatment decisions about their knee osteoarthritis found special challenges in patients using it, possibly due to their relatively low level of computer comfort.

Rochon D, Eberth JM, Fraenkel L, Volk RJ, Whitney SN. Elderly patients' experiences using adaptive conjoint analysis software as a decision aid for osteoarthritis of the knee. *Health Expect* 2012 Sept 20. Epub ahead of print.

Vanderbilt University Medical Center

The Vanderbilt CERT advanced the optimal use and awareness of therapeutics in vulnerable populations through research into the benefits and risks of treatments, including drugs, medical devices, and biological products. These vulnerable populations included children, elderly people, people with mental illnesses, people with low-incomes, and racial and ethnic minorities. Vanderbilt CERT researchers were also active in investigating the role of pharmaceutical marketing and current approaches to evaluating the comparative efficacy and safety of new medications.

Investigating co-prescribed medications. Proton-pump inhibitors, or PPIs, such as Prilosec, are used to reduce stomach acid, and clopidogrel (Plavix) is used to prevent blood clots. These two kinds of drugs are frequently prescribed to patients at the same time. But the benefits and harms of taking these two medicines at the same time are unclear. Researchers at the Vanderbilt University CERT examined the association between use of PPIs and clopidogrel and the risk of hospitalization for gastrointestinal bleeding and serious cardiovascular disease. They used automated data from Tennessee's Medicaid program to identify patients who received clopidogrel between 1999 and 2005 after they were hospitalized for heart attack, coronary artery disease, or angina. The dataset included 20,596 patients. A subset of 7,593 people were using clopidogrel and PPIs at the same time. To assess patients' medication use, researchers used automated records of dispensed prescriptions. They also looked at medical records for instances of hospitalization for gastrointestinal bleeding and serious cardiovascular disease. For patients with serious coronary heart disease who were treated with clopidogrel, concurrent PPI use was associated with reduced incidence of hospitalizations for gastrointestinal bleeding. The incidence of hospitalization among those taking both drugs was 50 percent lower than that for those who were taking clopidogrel alone. Patients who were taking both a PPI and clopidogrel did not have a statistically significant increased risk for serious cardiovascular disease.

Ray WA, Murray KT, Griffin MR, et al. Outcomes with concurrent use of clopidogrel and proton-pump inhibitors: a cohort study. *Ann Intern Med* 2010 Mar 16;152(6):337-45.

Weill Medical College of Cornell University

The Weill Cornell CERT, based in Cornell Medical College's Department of Public Health and in the Hospital for Special Surgery (HSS), focused on evaluating outcomes and cost-effectiveness of orthopedic and medical devices. The Weill Cornell CERT focused on building and maintaining a large registry of patients undergoing total joint replacements of their shoulders, hips, or knees. In 2011, the Weill Cornell CERT Total Joint Replacement registry continued its collection of data on outcomes to compare the effectiveness of joint replacement devices in different patient populations. As of 2011, there were approximately 30,000 patients enrolled in the registry—up from about 17,000 in 2007. This registry is distinctive in capturing patient perspectives on their procedures by virtue of its extensive collection of patient-reported outcomes data.

Racial Disparities in Joint Replacement. Primary arthroplasties (new joint replacement surgeries) have increased between 1996 and 2005, while the rates of arthroplasty revision (done when joint implants fail and need to be replaced) increased only slightly. Weill Cornell CERT researchers found racial disparities in the use of primary arthroplasties among the patients who receive these procedures. The racial disparities in use that were observed were greater than those seen with income disparities and were not confined to the elderly or low income populations, suggesting there may be an unmet need for these procedures among racial minorities.

Bang H, Chiu YL, Memtsoudis SG, et al. Total hip and total knee arthroplasties: trends and disparities revisited. *Am J Orthop* 2010 Sep;39(9):E95-102.

Summary

In 2011, the 14 CERT Research Centers across the United States addressed pressing questions about the use, safety, and effectiveness of therapeutics and medical devices and included studies that focused on children, the elderly, and other vulnerable populations.

The CERTs worked to improve prescribing and prevent adverse drug events.

The Brigham and Women's CERT found that error rates associated with computer-generated prescriptions were consistent with error rates for handwritten prescriptions, but that the number, type, and severity of computer prescribing errors varied by prescribing system, suggesting that prescribing systems can be improved to prevent errors. The Arizona CERT educated students, pharmacists and clinicians about safe prescribing practices, launching an interactive Continuing Medical Education module targeted to prescribers with the highest rates of writing inappropriate co-prescriptions for interacting drugs. University of Illinois at Chicago CERT researchers, building on previous work, programmed 24 "high priority pairs" of medications and lab test results into the clinical computer system at the University of Illinois hospital to provide daily alerts about situations in which patients' medications might be risky or when patients could be suffering an adverse event from medication.

The CERTs harnessed and evaluated new data resources and health information technology.

The University of Chicago CERT led a collaboration of Chicago area teaching hospitals to develop a data sharing infrastructure, laying the groundwork to support future hospital-based comparative effectiveness research. Houston CERT researchers tested a computer tool designed to improve decision making for patients considering knee replacement. The CERT tested the tool in a randomized controlled trial among patient groups receiving different combinations of decision aids, including printed information, a DVD, and the computer decision aid. The largest reduction in decision-making conflict was among patients who viewed the DVD alone, suggesting the new computer tool did not improve decision making.

The CERTs worked to improve medical outcomes for children and adolescents.

The Cincinnati Children's Hospital Medical Center CERT sought to improve outcomes for children with juvenile idiopathic arthritis with the Pediatric Rheumatology—Care and Outcomes Improvement Network (PR-COIN), a network that is developing and evaluating specific disease management strategies to improve care and determine how to incorporate these strategies into clinical practice. Researchers at the Rutgers CERT studied Medicaid data to understand how well medications were working to treat children with early-onset schizophrenia. They used Medicaid data from 45 States to examine differences in the use of newer antipsychotic drugs among children and adolescents with early-onset schizophrenia. They found that treatment with each of the medications was associated with a high risk of stopping treatment early and admission to a psychiatric hospital within 6 months of starting.

The CERTs evaluated promising new practices for older adults.

Researchers at the University of Alabama at Birmingham CERT found that allowing Medicare-eligible women to schedule themselves for a bone density test, in a process similar to the way women self-schedule for mammograms, significantly improved rates of osteoporosis screening. The University of Iowa CERT researchers found that collaboration between pharmacists and doctors worked to help older people control their blood pressure. Blood pressure control rates remained significantly higher following the intervention using doctor-pharmacist teams compared with blood pressure among patients who had usual care, even 18 months after the program ended.

The CERTs evaluated potential risks and benefits associated with medication use. The UPenn CERT found that early childhood use of antibiotics to treat anaerobic bacteria was associated with an increased risk of developing inflammatory bowel disease. The HMORN CERT examined how age, race, smoking and obesity might affect risk of infections associated with the drugs Infliximab (Remicade), and Etanercept (Enbrel), used to treat conditions such as rheumatoid arthritis and psoriasis. None of these characteristics affected the risk of infection, except age—there was an increased risk of serious infections associated with Infliximab for patients younger than 65. The Vanderbilt University CERT examined the consequences of using of two kinds of drugs that are frequently co-prescribed—Prilosec, to reduce stomach acid, and

clopidogrel (Plavix), to prevent blood clots. For patients with serious coronary heart disease who were treated with Plavix, use of Prilosec or similar drugs in the class of proton-pump inhibitors (PPIs) was associated with reduced incidence of hospitalizations for gastrointestinal bleeding. At the same time, the investigators noted that patients who took both a PPI and Plavix did not have an increased risk for serious cardiovascular disease.

The CERTs closely monitored medical devices.

The Weill Cornell CERT reported that this year, its Joint Registry, established to track outcomes of patients who have had a total joint replacement, grew to include 30,000 patients—up from about 17,000 in 2007. The registry contains an extensive collection of patient-reported outcomes data on these procedures that hold great potential in aiding future research. Also this year, Duke CERT researchers found that Medicare patients with heart failure who were eligible for an implantable cardioverter-defibrillator (ICD) and who received an ICD had a lower risk of death over the following 3 years than those who did not receive a device.

CERTs Publications

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